

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q94286

Koichi NAKANO, et al.

Appln. No.: 10/577,427

Group Art Unit: 1641

Confirmation No.: 4735

Examiner: NOT YET ASSIGNED

Filed: April 27, 2006

For: DIAGNOSTIC REAGENT FOR UTERINE ADENOCARCINOMA AND METHOD OF

DETECTING ADENOCARCINOMA CELLS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith (except for the U.S. patent), together with a copy of a Supplementary European Search Report for counterpart European Application No. EP 04 81 7413 wherein the listed documents were cited.

The present Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits, and therefore no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 10/577,427

Attorney Docket No.: Q94286

The submission of the listed documents is not intended as an admission that any such

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document constitutes prior art against the claims of the present application. Applicant does not

waive any right to take any action that would be appropriate to antedate or otherwise remove any

listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: July 18, 2007

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Substitute for Form 1449 A & B/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

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Application Number	10/577,427	-
Confirmation Number	4735	
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First Named Inventor	Koichi NAKANO	70
Art Unit	1641	13
Examiner Name	NOT YET ASSIGNE	D
Attorney Docket Number	Q94286	

	U.S. PATENT DOCUMENTS							
Examiner	Cite	Document	Number	Publication Date				
Initials*	No.1	Number	Kind Code ² (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document			
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_		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		SHITARA, KENYA et al, "APPLICATION OF ANTI-LUNG ADENOCARCINOMA	17.00
		MONOCLONAL ANTIBODY RECOGNIZING CYTOKERATIN-LIKE CYTOPLASMIC	1
		ANTIGEN FOR TUMOR DIAGNOSIS', ANTICANCER RESEARCH, vol. 12, no. 4, 1993, pages 1121 - 1129, XP008076503	
	·	DALLENBACH-HELLWEG, G., "INEW CYTOGENETIC CLASSIFICATION OF	
		PRECANCEROUS LESIONS AND CARCINOMAS OF THE ENDOMETRIUM: POSSIBILITIES	
		AND LIMITS OF IMMUNOHISTOCHEMICAL DIFFERENTIATION], VERHANDLUNGEN DER DEUTSCHEN GESELLSCHAFT FÜR PATHOLOGIE 1991, vol. 75, 1991, pages 357 - 362,	
		XP008076509	
		DALLENBACH-HELLWEG, G., et al, "THE VALUE OF IMMUNOHISTOCHEMISTRY IN THE	
		DIFFERENTIAL DIAGNOSIS OF ENDOMETRIAL CARCINOMAS", APMIS SUPPLEMENTUM, no. 23, 1991, pages 91 - 99, XP008076508	
		LANG, G., et al, "THE HISTOGENETIC ORIGIN OF CERVICAL MESONEPHRIC HYPERPLASIA	
		AND MESONEPHRI ADENOCARCINOMA OF THE UTERINE CERVIX STUDIED WITH	
		IMMUNOHISTOCHEMICAL METHODS", INTERNATIONAL JOURNAL OF GYNECOLOGICAL	
		PATHOLOGY, vol. 9, no. 2, 1990, pages 145 - 157, XP008076510	
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Examiner Signature	Date Considered	
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

Substitute for Form 144	9 A & B/PTO			Complete if Known		
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Examiner	Cite	Document Number		Bublication Data	
Initials*	No.1	Number	Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US			
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	FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Cite Foreign Patent Document		Publication Date	Name of Patentee or				
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	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶				
		ALKUSHI, A. et al, "IMMUNOPROFILE OF CERVICAL AND ENDOMETRIAL					
		ADENOCARCINOMAS USING A TISSUE MICROARRARY", VIRCHOWS ARCHIV: AN					
l		INTERNATIONAL JOURNAL OF PATHOLOGY MAR 2003, vol. 442, no. 3, March 2003 (2003 - 03),					
		pages 271 - 277, XP002425080					
Ī		IVANYL, D. et al, "KERATIN SUBTYPTES IN CARCINOMAS OF THE UTERINE CERVIX:	1				
j		IMPLICATIONS FOR HISTOGENESIS AND DIFFERENTIAL DIAGNOSIS", CANCER					
		RESEARCH, AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD, US, vol.					
		50, 1990, pages 5143 - 5152, XP001208062					
		MOLL, "CYTOKERATINS OF NORMAL EPITHELIA AND SOME NEOPLASMS OF THE FEMALE					
		GENITAL TRACT', LABORATORY INVESTIGATION, UNITED STATES AND CANADIAN					
		ACADEMY OF PATHOLOGY, BALTIMORE, US, vol. 49, no. 5, 1983, pages 599 - 610, XP008069877					
		ICHIMURA, T. et al, "IMMUNOHISTOCHEMICAL EXPRESSION OF GASTRIC MUCIN AND p53					
1		IN MINIMAL DEVIATION ADENOCARCINOMA OF THE UTERINE CERVIX", INTERNATIONAL					
ļ		JOURNAL OF GYNECOLOGICAL PATHOLGY: OFFICIAL JOURNAL OF THE INTERNATIONAL	ŀ				
į		SOCIETY OF GYNECOLOGOICAL PATHOLOGISTS JUL 2001, vol. 20, no. 3, July 2001 (2001 - 07),					
į		pages 220 - 226, XP008076521					
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TRADEM	IENTS				
Examiner	Cite	Document	Number	Publication Date	1
Initials*	No.	Number	Kind Code ² (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US			

FOREIGN PATENT DOCUMENTS							
Examiner	Cite	Foreign Patent Document			Publication Date	Name of Patentee or	
Initials*	No.1	Country Code ³	Number⁴	Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation ⁶
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		NON PATENT LITERATURE DOCUMENTS	
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		HATA, SAKAE et al, "DIAGNOSTIC SIGNIFICANCE OF ENDOCERVICAL GLANDULAR CELLS	
		WITH "GOLDEN-YELLOW" MUCIN ON PAP SMEAR", DIAGNOSTIC CYTOPATHOLOGY AUG	İ
		2002, vol. 27, no. 2, August 2002 (2002 - 08), pages 80 - 84, XP002425081	
		GOTOH, TOMOKO et al, "AN EXTREMELY RARE CASE OF ADENOMA MALIGNUM WITH	
		LARGE CYSTIC TUMOR WHICH RESULTED IN URINARY OBSTRUCTION", GYNECOLOGIC	
		ONCOLOGY FEB. 2002, vol. 84, no. 2, February 2002 (2002 - 02), pages 339 - 343, XP002425082	
		UTSUGI, KUNIKO et al, "UTILITY OF THE MONOCLONAL ANTIBODY HIK 1083 IN THE	
		DIAGNOSIS OF ADENOMA MALIGNUM OF THE UTERINE CERVIX", GYNECOLOGIC	
		ONCOLOGY, vol. 75, no. 3, December 1999 (1999 - 12), pages 345 - 348, XP002425083	
		ISHII, KEIKO et al, "CYTOLOGIC AND CYTOCHEMICAL FEATURES OF ADENOMA	
		MALIGNUM OF THE UTERINE CERVIX", CANCER, vol. 87, no. 5, 25 October 1999 (1999-10-25), pages 245 - 253, XP002425084	
			1

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Examiner Signature		_	Date Considered		

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Substitute for Form 1449 A	A & R/PTO			Сотр	olete if Known
Substitute for Form 1447 F	1 & 5/1 10			Application Number	10/577,427
PE INFORM	MATION DISC	LOS	URE	Confirmation Number	4735
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U.S. PATENT DOCUMENTS						
Examiner	Cite	Document Number		Publication Date		
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		US				
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		ZHAO, SHUMEI et al, "MUCIN EXPRESSION IN NONNEOPLASTIC AND NEOPLASTIC GLANDULAR EPITHELIA OF THE UTERINE CERVIX", INTERNATIONAL JOURNAL OF GYNECOLOGICAL PATHOLOGY: OFFICIAL JOURNAL OF THE INTERNATIONAL SOCIETY OF GYNECOLOGICAL PATHOLOGISTS OCT 2003, vol. 22, no. 4, October 2003 (2003 - 10), pages 393 - 397, XP008076522	
		YAMASHITA S. et al, "CLINICOCYTOPATHOLOGICAL AND IMMUNOHISTOCHEMICAL STUDY OF ADENOMA MALIGNUM OF THE UTERINE CERVIX", HIROSHIMA JOURNAL OF MEDICAL SCIENCES DEC 2000, vol. 49, no. 4, December 2000 (2000 - 12), pages 167 - 173, XP008076520	
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Examiner Signature	Da	ate Considered

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